Supreme Court, U.S.
FILED
JUN 26 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-1922

In The

Supreme Court of the United States

October Term, 1988

SCHERING CORPORATION,

Petitioner,

vs.

OPTICAL RADIATION CORPORATION,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

CHRISTIE, PARKER & HALE
EDWIN L. HARTZ
THOMAS J. DALY
350 West Colorado Boulevard
Suite 500
Pasadena, CA 91105
(818) 795-5843

Attorneys for Respondent
OPTICAL RADIATION CORPORATION

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

RULE 28.1 STATEMENT

Respondent, Optical Radiation Corporation, has no affiliated corporations.

TABLE OF CONTENTS

Page

STATEMENT OF THE CASE 1

1. Entitlement to Earlier Filing Date 2

2. Obviousness 2

3. Infringement 3

4. Inequitable Conduct 4

REASONS FOR DENYING THE WRIT 5

I. The Decisions Below Are Not In Conflict With The Applicable Decisions Of This Court 6

A. The Federal Circuit Did Not Engage In Its Own Fact Finding 6

B. The District Court's Obviousness Analysis Was In Accord With This Court's Precedent 7

C. The District Court's Treatment Of ORC's Patent Application Followed Well Established Precedent 8

II. The Decisions Below Gave Full Consideration To The Issues Raised By Schering And Decided Them Correctly 10

A. The Prior Art Combined Was Analogous Prior Art 10

B. Schering Cannot Add A "Soft Lens" Limitation to the Claims to Avoid Invalidity..... 11

C. The District Court's Resolution Of the Level of Ordinary Skill In The Pertinent Art Was Amply Supported By The Record 11

TABLE OF CONTENTS – Continued

Page

III. The Issues Raised By Schering Are Not Sufficiently Important To Warrant This Court's Attention 12

CONCLUSION 13

TABLE OF AUTHORITIES

Page

CASES

Graham v. John Deere Co., 383 U.S. 1 (1966) 3, 7, 10

Graver Tank & Manufacturing Co. v. Linde Air Products Co., 336 U.S. 271 (1949) 11

Haughey v. Lee, 151 U.S. 282, 285 (1894) 9

Lear v. Adkins, 395 U.S. 653 (1969) 8, 9

Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1582 (Fed.Cir. 1983) 9

Panduit Corp. v. Dennison Manufacturing Co., 475 U.S. 809, *on remand*, 810 F.2d 1561, 1565 (Fed.Cir. 1987) 7

Paramount Publix Corp. v. American Tri-Ergon Corp., 294 U.S. 464, 477 (1935) 9

Rice v. Sioux City Memorial Park Cemetery, 349 U.S. 70, 74 (1955) 12

STATUTES

35 U.S.C. § 103 3

Rule 35 of the Federal Circuit Rules 5

MISCELLANEOUS

2 D. Chisum, *Chisum on Patents*, § 5.05[5] at 5-256 to 57 (1985) 9

No. 88-1922

In The

Supreme Court of the United States

October Term, 1988

SCHERING CORPORATION,

Petitioner,

vs.

OPTICAL RADIATION CORPORATION,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

Respondent respectfully opposes the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in its cause No. 88-1227-1267. No special and important reason exists that would justify a review on writ of certiorari.

STATEMENT OF THE CASE

Schering Corporation (Schering) brought an action against Optical Radiation Corporation (ORC) in the

United States District Court for the Central District of California for infringement of United States Patent No. 4,390,676 (Loshaek '676 patent). Four principal issues were raised during the extensive court trial as follows:

1. Entitlement to Earlier Filing Date

The claims of the Loshaek '676 patent are directed to a lens for use by aphakics "in contact with the eye." The quoted language was inserted to cover contact lenses and intraocular lenses (IOLs), lenses surgically implanted in a patient's eye to replace a removed crystalline lens (an aphakic is a person who has had the crystalline lens removed). To avoid certain prior art, however, the Loshaek '676 patent would have to be entitled to the filing date of an earlier application that indicated the "invention [was] applicable to contact lenses and to lenses to be used in spectacles." Although no reference was made to IOLs in this earlier application, the district court decided that the Loshaek '676 patent would be entitled to the earlier filing date.

2. Obviousness

The claims of the Loshaek '676 patent cover a lens for use by aphakics, made of a polymer where an ultraviolet light (UV) absorber has been copolymerized with a material suitable for making a lens. No limitation to hard or soft lenses is contained in the claims. The prior art to the Loshaek '676 patent included contact lenses where a UV absorber was mixed, but not copolymerized, with the material from which the lens was formed and the Fertig

references, viz., United States Patent No. 3,173,893 issued to Fertig et al. and an article in the *Journal of Applied Polymer Science*, Vol. 10, pp. 663-672 (1966) authored by Fertig and others, which disclosed methods for copolymerizing UV absorbers into a wide variety of plastic articles. Although the Fertig references did not specifically mention lenses, they did highlight the advantages of copolymerization in achieving a complete lack of toxicity and the total absence of UV absorber migration from polymers. One of the polymers discussed in the Fertig references is a polymer comprising a specific commercially available UV absorber copolymerized with the standard material for contact lenses and IOLs; this identical polymer is set forth as an example in the Loshaek '676 patent. The district court, following this Court's analysis in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), decided that claims 1 and 2 of the Loshaek '676 patent were invalid for obviousness under 35 U.S.C. § 103.

3. Infringement

The UV absorber used by ORC in its IOLs is a powder-like substance, called Compound 400, that itself is a copolymer and cannot be copolymerized with the material used to form the lens. Instead, unlike the UV absorber of the Loshaek '676 patent, it is physically trapped in the shaped lens body. The district court decided that ORC did not infringe any of the claims of the Loshaek '676 patent.

4. Inequitable Conduct

A brochure disclosing the contact lenses in which a UV absorber was mixed with the material from which the

lens was formed was not revealed to the United States Patent and Trademark Office (PTO) during the prosecution of an application related to that upon which the Loshaek '676 patent issued even though the inventor, Loshaek, was aware of this brochure and specifically brought it to the attention of his patent attorney. This brochure, disclosing a UV absorbing contact lens, was withheld by Loshaek and his attorney while arguing to the PTO that the reference relied on by the PTO did not disclose a UV absorbing contact lens. The district court decided that the Loshaek '676 patent was unenforceable due to inequitable conduct.

Schering appealed the district court's decisions on obviousness, infringement and inequitable conduct. ORC appealed the district court's decision on the Loshaek '676 patent's entitlement to the earlier filing date. On January 27, 1989, the United States Court of Appeals for the Federal Circuit issued a decision affirming the district court's finding that claims 1 and 2 of the Loshaek '676 patent were invalid for obviousness. The Federal Circuit reversed the finding that the Loshaek '676 patent was unenforceable due to inequitable conduct. The finding that ORC had not infringed the Loshaek '676 patent and the finding that this patent was entitled to an earlier filing date were not reached by the Federal Circuit because of its affirmance of the finding of obviousness, which affirmance is questioned by Schering.

The Federal Circuit decision was not prepared for publication in a printed volume because, as is stated on the decision, it does not add significantly to the body of law and is not of widespread interest. Schering's petition for rehearing was denied. Schering also petitioned for

rehearing in banc. Rule 35 of the Federal Circuit Rules provides that for a case to merit rehearing in banc it must require either answer to a precedent-setting question of exceptional importance or resolution of a conflict between the panel opinion and precedent of this Court or of the Federal Circuit. The petition for rehearing in banc was denied.

REASONS FOR DENYING THE WRIT

The petition for a writ of certiorari should be denied. The Federal Circuit decision is not in conflict with the applicable decisions of this Court. No findings of fact were made by the Federal Circuit. The district court used a syllogism to conveniently organize and illustrate its conclusion on obviousness, a conclusion reached through an analysis based on this Court's decision in *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and properly affirmed by the Federal Circuit. The district court treatment of ORC's patent application followed well established precedent of this Court and needed no correction by the Federal Circuit.

The Federal Circuit decision below gave full consideration to the issues now raised by Schering and decided them correctly. The prior art considered by the district court was analogous prior art properly combined in the determination of obviousness. Claims 1 and 2 of the Loshaek '676 patent are not limited to soft lenses and this limitation cannot be added by Schering to avoid invalidity. The level of ordinary skill used by the district

court in the determination of obviousness was fully supported by the record.

The issues raised by the petition for writ of certiorari are not sufficiently important to warrant this Court's attention. These issues, although important to the parties, are based upon facts peculiar to this case and not likely to reoccur. There is no public importance associated with the outcome of this case.

I. The Decisions Below Are Not In Conflict With The Applicable Decisions Of This Court

A. The Federal Circuit Did Not Engage In Its Own Fact Finding

Schering asserts that the Federal Circuit improperly made its own factual findings in stating " . . . a UV absorber leaching problem was known to exist for plastic lenses using 'unbound' nonpolymerized absorbers. . . ." This statement is consistent with the findings of the district court and the specific prior art considered by the district court in finding the claimed invention to be obvious.

It is stated in the district court opinion that:

> "It is well known that if the UV absorber is polymerized with the monomer suitable for making a lens, it is less likely (if at all) to leach out of the lens than is a UV absorber that is nonpolymerizable and thus is not chemically bound within the lens." [A17]

The district court made this finding based on the Fertig references that teach that there had been problems with unbound nonpolymerized absorbers leaching from plastic. Fertig states:

> "In the addition of stabilizing agents to plastic materials, problems such as incompatibility, migration, volatility, and/or solvent extraction of the additive frequently arise."
>
> "In recent years there has been increasing interest in the synthesis of ethylenically unsaturated ultraviolet absorbers which could be copolymerized, thereby permanently incorporation a stabilizing moiety into a polymer. This approach would minimize problems such as incompatibility, migration, volatility and solvent extraction."

Fertig notes the problem and teaches the solution as found by the district court. Thus, the statement of the Federal Circuit was an accurate summary of the findings made by the district court, which findings were fully supported by the record. The Federal Circuit is well aware of the scope of appellate review and the prohibition against substituting its findings for those of the trial court. See *Panduit Corp. v. Dennison Manufacturing Co.*, 475 U.S. 809, *on remand,* 810 F.2d 1561, 1565 (Fed.Cir. 1987).

B. The District Court's Obviousness Analysis Was In Accord With This Court's Precedent

A close review of the district court opinion will reveal that the district court followed the test for obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) to the letter [A15-23]. The scope and content of the prior art were determined [A16-18]. The level of ordinary skill in the pertinent art was resolved [A19]. The differences between the prior art and the claims at issue was ascertained [A19-20]. Against this background, the obviousness or nonobviousness of the subject matter was

determined [A20]. In reaching its conclusion of obviousness, the district court used a syllogism as a convenient method of organizing and summarizing its determination. However, the syllogism arose out of the *Graham* analysis and did not replace it. Finally, such secondary considerations as were relevant were reviewed to give light to the circumstances surrounding the origin of the subject matter sought to be patented [A20-23].

The Federal Circuit decision affirming the district court's obviousness determination in no way sanctioned an improper test for obviousness. It properly validated an analysis fully in accord with this Court's precedent.

C. The District Court's Treatment Of ORC's Patent Application Followed Well Established Precedent

Schering would have this Court believe that the trial judge ignored the patent application filed by ORC as a secondary consideration by some sort of misapplication of this Court's decision in *Lear v. Adkins*, 395 U.S. 653 (1969).

The district court considered *Lear v. Adkins* in connection with the possibility of ORC being estopped to contest the validity of the claims of the Loshaek '676 patent.

The district court stated in its decision that:

> "If the only relevant considerations were the relationships between these two parties, I would be inclined to conclude that the defendant's conduct has estopped it to deny the validity of the plaintiff's patent. However, in *Lear v. Adkins*, 395 U.S. 653 (1960), the Court refused to allow such an estoppel to

> be imposed upon the licensee of a patent in an infringement action brought by the licensor. The reasoning of the opinion is clearly applicable to the present situation. [A22]

Thus, by applying the reasoning in *Lear v. Adkins*, the district court concluded that ORC was not estopped to contest the validity of Schering's patent just because ORC filed its own patent application. The district court clearly considered the secondary considerations, including ORC's patent application, in connection with the issue of obviousness.

Professor Chisum expresses the opinion that the "public policy favors challenges to the validity of patents, and no defendant in an infringement suit should be placed under a special handicap in raising the issue." 2 D. Chisum, *Chisum on Patents*, § 5.05[5] at 5-256 to 57 (1985). This Court, in holding that a defendant is not estopped from asserting the invalidity of a patent by virtue of its conduct in seeking to procure a patent for substantially the same invention, also recognized the public policy consideration expressed by Professor Chisum as follows:

> "[T]he defense of want of patentable invention in a patent operates not merely to exonerate the defendant, but to relieve the public from an asserted monopoly, and the court cannot be prevented from so declaring by the fact that the defendant had ineffectually sought to secure the monopoly for himself."

Haughey v. Lee, 151 U.S. 282, 285 (1894). *See also Paramount Publix Corp. v. American Tri-Ergon Corp.*, 294 U.S. 464, 477 (1935).

The Federal Circuit has also addressed itself to this issue. In *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721

F.2d 1563, 1582 (Fed.Cir. 1983), Chief Judge Markey stated:

> "Medtronic did not prove that CPI [the alleged infringer] knew of Witzke [a prior art reference] when it filed an application . . . on a device similar to that claimed in Walmsley [one of the patents in suit]. Further, if it be assumed that CPI once viewed an invention like Walmsley's nonobvious, that assumption could not foreclose a court from reaching a contrary conclusion in light of the entire record. [Bracketed material added.]

Not giving estoppel effect to a secondary consideration is not the same as ignoring that consideration. According weight to a secondary consideration in relation to all the facts as done by the district court is supported by this Court's decisions, prior decisions of the Federal Circuit and commentators.

II. The Decisions Below Gave Full Consideration To The Issues Raised By Schering and Decided Them Correctly

A. The Prior Act Combined Was Analogous Prior Art

Schering suggests that two lines of non-analogous prior art, one line relating to contact lenses having a UV absorber added and the other line relating to plastic articles with copolymerized UV absorbers added, were improperly combined in determining obviousness. In *Graham v. John Deere Co.*, 383 U.S. 1, 35 (1966), this Court concluded that prior art related to the problems confronting the inventor would be pertinent prior art. In the present case, Loshaek, a polymer chemist, was confronted

with the problems of adding a UV absorber to a contact lens and preventing the UV absorber from leaching from that lens. Surely, the Fertig references discussing the use of copolymerizable UV absorbers to prevent leaching were pertinent prior art.

B. Schering Cannot Add A "Soft Lens" Limitation to the Claims to Avoid Invalidity

Schering argues that the district court failed to consider the invention as a whole because the prior art considered by the district court would not have made it obvious to use a copolymerizable UV absorber in soft lenses, as opposed to the hard lenses specifically addressed by the prior art. However, the claims at issue are not limited to soft lenses, a fact apparently recognized by Schering. Thus, what Schering is actually attempting to do is add a "soft lens" limitation to its claims to avoid the invalidity determination. This Court has previously rejected such attempts. *See Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 336 U.S. 271, 277 (1949). No reason exists for overturning this well established precedent.

C. The District Court's Resolution Of the Level Of Ordinary Skill In The Pertinent Art Was Amply Supported By The Record

With regard to level of skill, the district court considered the level of skill and found that a person of ordinary skill in the art would have the training and skills of a polymer chemist.

The people involved in 1973, at the time of the filing of the prior application, in the design of plastic for use in contact lenses were scientists – specifically polymer chemists. Polymer chemists that were involved in 1972/1973 include Drs. Loshaek, Refojo, Gaylord, Hamm and Shen; all chemists, not medical doctors or ophthalmologists, with years of experience in plastics (polymers). Loshaek, Hamm and Shen were employees of Wesley Jessen Contact Lens Co. (Schering). Polymer chemists that were involved in the development of UV absorbing IOLs in the 1980-1982 time period, when Schering filed its C-I-P application and added IOLs to the specification and claims that became the Loshaek '676 patent, included Tom Posin and Donald Lawson, the chemists involved in developing the accused infringing product, i.e., ORC's UV IOL.

Thus, the district court evaluated obviousness using a level of skill amply supported by the record and not that of some "super scientist".

III. The Issues Raised By Schering Are Not Sufficiently Important To Warrant This Court's Attention

This Court does not sit for the benefit of the particular litigants, but rather only when there are special and important reasons therefor. *Rice v. Sioux City Memorial Park Cemetery*, 349 U.S. 70, 74 (1955). The phrase "special and important reasons" implies a reach to the problem beyond the academic or the episodic. *Id.* By Schering's own admission, the present case "is extremely unusual and unique." This certainly suggests that the present

case, while of great importance to the particular litigants, is peculiar to its facts and unlikely to reoccur.

Although Schering asserts that the decisions below are in conflict with this Court's precedent, no conflicts are actually present. Therefore, all that remains is yet another review of fact-bound determinations that will have no import beyond the parties to the case. In fact, a reversal of the Federal Circuit decision on obviousness may have no impact on the particular parties, depending upon the subsequent determinations made on infringement and the Loshaek '676 patent's entitlement to an earlier filing date that the Federal Circuit will then have to reach.

CONCLUSION

Schering's petition for a writ of certiorari should be denied. The decisions for which review is sought are not in conflict but rather in accord with the well established precedent of this Court. These decisions were also correctly decided. Finally, the issues raised by Schering, when properly evaluated, are not sufficiently important to warrant this Court's review.

Respectfully submitted,

CHRISTIE, PARKER & HALE
EDWIN L. HARTZ
THOMAS J. DALY
350 West Colorado Boulevard
Pasedena, CA 91105
(818) 795-5843
Attorneys for Respondent
Optical Radiation Corporation